

[0050] Referring now to Table 1 below, the subjective, patient determined data for a monofrequency tinnitus phase shift patient treatment study for twenty-three patients is reported. Table 1 reports on a clinical single blind study which was conducted in New York under the direction and control of Applicant.

[0051] A brief description of the study methodology hopefully will set the stage to more fully understand the data reported in Table 1. Patient volunteers with monofrequency tinnitus only were selected through responses to newspaper advertisements. Each patient completed a consent form agreeing to come to the designated office once a week for eight weeks to participate in a single blind study in which 50% of the study group would initially receive Applicant's sound cancellation tinnitus treatments and the other 50% would initially receive a placebo or sham treatment. After four weeks there would be a cross-over, i.e. the sham treatment group would begin receiving Applicant's sound cancellation treatments and the previously treated group would receive during the same period only sham treatments.

[0052] Each patient was asked to keep a daily tinnitus diary or log of his/her subjective estimate of tinnitus intensity on a scale of 1-10, with 10 being the patient's own usual level of tinnitus tone and 1 being minimal or negligible tinnitus tone intensity. Each patient was asked to make recordings daily at 0800 and 1600 hours respectively. At the initial screening session, a relevant patient medical history was obtained and the program methodologies were fully explained. At each weekly treatment session, each patient was asked to deliver their respective diaries to a program staff assistant, but they were not shown or discussed with the physician or audiologist administering the test or to Applicant.

[0053] Each patient was "sound-typed" as hereinabove explained in connection with FIG. 3 with each patient manipulating an adjustable frequency (tone) dial on an Agilent 33250a generator or its commercial equivalent. Each patient then similarly determined the amplitude or loudness of his/her tinnitus tone. These steps were repeated a number of times to ensure the accuracy of a patient's sound typing data and tests were repeated if a particular patient's results varied from try to try by more than 10% until exact determinations were assured. Care was taken to avoid octave confusion where sound typing may result in a frequency which is a multiple or submultiple of the actual tinnitus tone.

[0054] Applicant's frequency cancellation tinnitus treatment began with the patient's sound type data being set up on a first sound generator and like tone and amplitude data then set up on a second sound generator (see FIG. 1, sound generators 16 and 10 respectively) and the output wave forms from sound generators 16 and 10 coupled as inputs to an oscilloscope 14. With identical wave forms from sound generators 16 and 10 displayed on the oscilloscope 14, the phase shift knob 20 of sound generator 10 is utilized to shift the phase of output wave form of sound generator 10 directly or essentially in a single continuous movement into a reciprocal, 180 degree relationship with the output of sound generator 16. By summing the output wave forms from sound generator 16 and the phase shifted tone output from sound generator 10, the phase shifted reciprocal relationship of the two wave forms (See FIG. 2) can be observed and then the phase shifted wave form from sound generator 10

is also sent to the patient's auditory system via headphones 12 for a treatment period of 10 minutes. For the placebo or control group treatments, the sound wave was not phase shifted but set at a steady level of 100 hertz at 50 millivolts for a treatment period of 10 minutes. At the beginning and end of each treatment session, the patient's tinnitus tone amplitude was again subjectively determined, as hereinabove described.

[0055] To simplify summary study data entry in Table 1, the following conventions were utilized to characterize each patient's subjective tinnitus status which were then combined following completion of the eight weekly treatments into the following categories: 1=Excellent—complete or near complete relief with loudness reduction of 90% or more; 2=Very Good—strong partial relief response in the order of 75% loudness reduction; 3=Good—partial relief response in the order of 50% loudness reduction; 4=Fair—partial relief in the order of 25% loudness reduction; and 5=Poor—minimal or no relief from original tinnitus condition.

[0056] Referring now to Table 1, as is shown of the twenty-three treated patients, seven patients experienced complete or nearly complete relief (1 s); four patients experienced strong partial relief (2s) with loudness reduced in the order of 75%; eight patients experienced good partial relief (3s) with loudness reduced in the order of 50%; one patient experienced partial relief with loudness reduced in the order of 25% (4); and three patients experienced no or negligible relief from their original tinnitus condition (5s). None of the patients experienced any increase or aggravation of his/her original tinnitus condition. As shown, the study encompassed a wide range of tinnitus tone levels and a wide range of individuals who had suffered from tinnitus for many years.

[0057] It is important in evaluating the Table 1 data to recognize that the response of all of the placebo or control patients was a #5—minimal or no relief response from their respective original monofrequency tinnitus condition (5s). When compared to the nineteen responses in the treated patient group of twenty-three patients, it is statistically very significant and yields a p-value of $p=0.001$.

[0058] As is well known in the medical arts, tinnitus has many different forms and different causes. A survey of medical tinnitus treatment literature clearly demonstrates how difficult a problem treating tinnitus patients truly has been over the years and that there is currently no known cure for tinnitus. Vernon has recently reported in 1998 that early optimistic reports of tinnitus cures in the order of 80% are in drastic contrast to more humble results from various other recent clinical experiences. However, for those who suffer substantial medical disability from tinnitus, any, even temporary relief can be significant even if their tinnitus is not completely or permanently cured. The data of Table 1 demonstrates that a total of nineteen treated patients (82%) achieved at least a 50% reduction in their tinnitus loudness and more than 30% reported complete or nearly complete (more than 90% loudness reduction) relief.

[0059] While the tinnitus patient treatment study reported in Table 1 utilized primarily the embodiment of Applicant's improved treatment apparatus and methods which utilizes direct or one-step phase shift cancellation adjustments, the other sequential, incremental-step phase shift adjustments